

**MAZIE SLATER KATZ & FREEMAN, LLC**  
COUNSELLORS AT LAW  
103 Eisenhower Parkway  
Roseland, NJ 07068  
(973) 228-9898  
Fax (973) 228-0303  
[www.mazieslater.com](http://www.mazieslater.com)

David A. Mazie\*  
Adam M. Slater\*<sup>o</sup>  
Eric D. Katz\*<sup>o</sup>  
David M. Freeman  
Beth G. Baldinger  
Matthew R. Mendelsohn<sup>o</sup>

Karen G. Kelsen<sup>o</sup>  
Cheryll A. Calderon  
David M. Estes  
Adam M. Epstein<sup>o</sup>  
Michael R. Griffith<sup>o</sup>  
Matthew Tonzola  
Christopher J. Geddis

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\*Certified by the Supreme Court of  
New Jersey as a Civil Trial Attorney

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<sup>o</sup>Member of N.J. & N.Y. Bars

December 5, 2019

**VIA ECF**

Honorable Joel Schneider  
United States Magistrate Judge  
U.S. District Court - District of New Jersey  
Mitchell S. Cohen Building & US Courthouse  
1 John F. Gerry Plaza, Courtroom 3C  
4th and Cooper Streets  
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS  
LIABILITY LITIGATION  
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Plaintiffs provide the following Letter Brief concerning custodians, search terms, ESI related issues, and document request to Manufacturer Defendants.

**I. INTRODUCTION**

Before the Court are three outstanding discovery-related issues. These issues pertain 1) to the written discovery requests (and objections) to the five “manufacture defendants” – (i) ZHP, (ii) Mylan, (iii) Teva, (iv) Aurolife, and (v) Torrent, 2) the custodians for these manufacture Defendants (as well as regulatory agent Hetero USA), and 3) the search terms the

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Defendants will use to run against the selected custodians' files. The parties have engaged in exhaustive, months-long meet-and-confers calls and conferences about these three issues.

## **II. BACKGROUND**

### **A. Document Requests**

Plaintiffs served their first set of requests for the production of documents ("RFPDs") to the Manufacturer Defendants on August 30, 2019. Defendants served a litany of identical<sup>1</sup>, boilerplate objections on October 15, 2019.<sup>2</sup> Shortly thereafter, Plaintiffs dutifully commenced meet-and-confers with Defendants about their objections and responses. Following the Court's stern admonition, Defendants served amended objections and responses on November 18 and 20, 2019. Plaintiffs engaged in additional discussions with Defendants following receipt of Defendants' amended objections and responses.

The meet-and-confer process has been, in a word, disappointing. Defendants' counsel presumes their mere presence on calls, without more, is sufficient participation. Numerous attempts by Plaintiffs to offer or seek clarification from Defendants have resulted in zero post-call efforts on Defendants' parts. Plaintiffs' questions about Defendants' objections and inquiries into what Defendants will or will not produce are generally met with silence, and no follow-up. In an attempt to confer in good faith, in some instances Plaintiffs even provided detailed letters to identify, with more specificity, the types of documents maintained in the

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<sup>1</sup> The objections were so remarkably identical that in certain instances defendants failed to remove the drafting defendant's name and replace it with their own name.

<sup>2</sup> Hetero USA never served objections or responses because it has taken the position that it is not an API or finished dose manufacturer, but rather a different Hetero entity in India is. Hetero USA did, however, participate in core discovery, and has provided a list of ESI custodians, but has otherwise not participated in discussions regarding search terms, and the like.

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ordinary course of business that Plaintiffs would expect to be responsive to their RFPDs. *See* Ex. 1 (Plaintiffs' Ltr. re Manufacturing), Ex. 2, (Plaintiffs' Ltr. re Sales and Pricing).

In an effort to kick-start the meet-and-confer process, Plaintiffs re-formulated certain Requests over the Thanksgiving holiday and served those upon Defendants on November 29, 2019, in an effort to streamline Plaintiffs' requests, to conform with the Court's earlier guidance, and to offer compromises on various requests. Defendants largely rebuffed these efforts, instead claiming these *narrowed* requests somehow frustrated the already-lengthy meet-and-confer process.

Nevertheless, Plaintiffs have attempted to narrow many of their requests or, in the interest of compromise (and with the benefit of the Court's recent email guidance of December 2, 2019), Plaintiffs have agreed to an even further narrowing of their RFPDs. An appendix with these further narrowed requests is attached hereto (*See* Appendix), and a redline comparison is attached at Ex. 3. The handful of requests and subject areas requiring the Court's attention are set forth *infra* Part IV.A.

**B. Custodians**

The Court ordered Defendants to produce lists of proposed custodians on September 15, 2019. D.E. 185. In response to this order, Defendants, who are multinational corporations with facilities and offices around the world, provided Plaintiffs with woefully inadequate lists.<sup>3</sup> Understanding that these lists were obviously going to require drastic and immediate supplementation, Plaintiffs immediately began requesting organizational charts or similar

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<sup>3</sup> By way of example, ZHP proposed a mere 7 custodians in their initial September 23, 2019, proffer. *See* Ex. 18.

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information to assist in the identification of ESI custodians. Plaintiffs also provided Defendants with lists of proposed custodians, even going so far as to identify the bates ranges in *Defendants' own documents* where these custodians' names were found. *See* Ex. 21. For their part, Defendants initially refused to produce any organizational charts, claiming they were outside the scope of the Court's Core Discovery Order. Then, Defendants, incredibly claimed they did not possess any organizational charts or similar information. Finally, some (but not all) Defendants began to trickle production of organizational charts for certain departments, for more recent time periods. For the API Defendants (ZHP and Mylan), the Parties have, only now, begun the process of working to identify the relevant custodians involved in quality assurance and quality control capacities at the finished dose manufacturing facilities, as prior to the Court's ruling on Macro discovery, the API Defendants refused to discuss finished dose manufacturing.

Nevertheless, Plaintiffs did their best to identify custodians based on review of Defendants' core discovery (which, by definition, was narrowly limited to documents to or from the FDA) and, eventually, the limited organizational charts produced by Defendants. The parties have had multiple meet-and-confers about each Defendant's ESI custodians. The current status of custodians as to each Defendant is addressed *infra* Part IV.B.

**C. Search Terms**

Plaintiffs first presented their proposed search terms to Defendants on September 16, 2019. Plaintiffs' terms were largely informed by their review of Defendants' core discovery productions, and documents obtained from the FDA pursuant to FOIA requests. After repeated requests to confer on search terms, Defendants finally agreed to talk about a month later in October. Defendants provided their first counter-proposal for search terms on October 30, 2019.

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The parties had multiple subsequent discussions thereafter, with the most recent discussion on December 3, 2019.

One of the central impediments to those negotiations imposed by Defendants was their refusal to collect any custodial documents to run test searches (even for those custodians identified by Defendants as proper in their limited and preliminary September custodial lists). These test searches would have served to both establish hit counts and give guidance regarding disputed terms, as well as to confirm that a proposed custodian did or did not have relevant custodial documents. This refusal is part of Defendants' apparent strategy to deepen and then take advantage of Plaintiffs' significant knowledge gaps. Similarly, Defendants failed to produce exemplar internal documents (including those documents provided to the FDA as part of the FDA's inspections of their respective facilities) related to clearly admissible evidence to assist Plaintiffs in identifying custodians and key terminology.

Instead, Defendants have simply speculated which terms *may* be overbroad because they *may* result in too many false positives, or *may* hit on too many responsive but tangentially relevant documents. Not only has Defendants' approach frustrated the productivity of the search term meet-and-confer process, but it violates the spirit if not the letter of the Federal Rules. *See, e.g., Aikman*, 256 F.R.D. at 418 ("The concept of sampling to test both the cost and the yield is now part of the mainstream approach to electronic discovery.").

Despite Defendants' refusal to run any hit count reports or samples for any search terms, Plaintiffs have endeavored to work with Defendants by reducing or modifying their list of proposed terms, and, in fact did so. Plaintiffs' operative lists of terms and modifiers are attached as Ex. 29 and Ex. 30, and are discussed more fully *infra* Part IV.C.

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**D. ESI/Document Retention**

Plaintiffs continue to lack significant amounts of information concerning Defendants' computer and information storage systems and data retention, making all the meet-and-confers about custodians, search terms, and Plaintiffs RFPDs much more difficult. This issue is discussed more fully *infra* Part IV.D.

**III. APPLICABLE STANDARDS**

The Federal Rules provide for broad and liberal discovery. *In re Madden*, 151 F.3d 125, 138 (3d Cir. 1998) ("Pretrial discovery is....accorded a broad and liberal treatment.") (internal quotations and citation omitted); Wright, Miller & Marcus, Federal Practice & Procedure, Civil 2d § 2007 ("The rule does allow broad scope to discovery and this has been well recognized by the courts."). Rule 26(b)(1) provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b) (amended effective Dec. 1, 2015). "Information within this scope of discovery need not be admissible in evidence to be discoverable." *Id.*<sup>4</sup> More detailed, issue-specific standards (e.g., relating to document requests, custodians, or search terms) are set forth as appropriate in Part IV below.

**IV. ARGUMENT**

**A. Document Requests**

The party resisting the production of documents bears the burden of establishing lack of relevance, undue burden, or some other appropriate basis. *See, e.g., Fattone v. Burger*, Civ. A.

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<sup>4</sup> The 2015 amendments to the Federal Rules did not alter this "clear focus" of Rule 26(b), which has been the same and in effect since the 1983 revisions to the rule. *See* Fed. R. Civ. 26(b) advisory comm. notes (2015).

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No. 2:12-cv-1691, 2015 WL 4608061, at \*2-3 (W.D. Pa. July 31, 2015) (Ex. 34). A resisting party or non-party must clearly demonstrate the basis for withholding the discovery; generalized allegations or speculation will not satisfy this burden. *See, e.g., Josephs v. Harris Corp.*, 677 F.2d 985, 992 (3d Cir. 1982) (“Mere recitation of the familiar litany that an interrogatory or a document production request is overly broad, burdensome, oppressive and irrelevant will not suffice.”); *Fattone*, 2015 WL 4608061, at \*3.

Importantly, the Federal Rules explicitly require a party that objects to a request (in whole or in part) to state “whether any responsive materials are being withheld on the basis of that objection.” Fed. R. Civ. P. 34(b)(2)(C). As the Advisory Committee notes explain,

[A]n objection to a Rule 34 request must state whether anything is being withheld on the basis of the objection. This amendment should end the confusion that frequently arises when a producing party states several objections and still produces information, leaving the requesting party uncertain whether any relevant and responsive information has been withheld on the basis of the objections. The producing party does not need to provide a detailed description or log of all documents withheld, but does need to alert other parties to the fact that documents have been withheld and thereby facilitate an informed discussion of the objection.

Fed. R. Civ. P. 34, Adv. Comm. Notes 2015 Amend.

Defendants’ objections, even as amended, continue to obscure what documents they will produce and what, if anything, they will be withholding in response to particular document requests in a clear violation of Rule 34 and the above-cited case law. For instance, ZHP re-writes numerous requests and specifies narrow categories of documents that it will produce, without identifying what if anything it is withholding. ZHP’s tactic has even spilled over into its compliance with the Court’s recent macro discovery issues order. *See* D.E. 303. Recently, on at least two separate meet-and-confer calls, the Defendants refused to identify or even commit to

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identifying at some point in the future, how they will construe “potential nitrosamine contamination”<sup>5</sup> as the Court set forth in its order compelling the API Defendants to produce such documents. *Id.* For other requests, Defendants simply claim they will continue to “meet-and-confer” about the scope of what might be produced.

Enough is enough. The meet-and-confer process cannot go on indefinitely (absent a commitment to immediate rolling production of unobjectionable documents), especially when Defendants’ participation in such meet-confers stretches the boundaries of good faith. Plaintiffs served their requests in August. The Court warned Defendants repeatedly that all discovery disputes will be resolved at the December 11, 2019, CMC. If Defendants could not articulate over the last 3.5 months, what they would or would not produce, then there is no proper basis for their objections and withholding of responsive documents.

Notwithstanding Defendants’ tactics, Plaintiffs believe they have reached some compromises on certain requests (or can live with Defendants’ unilateral narrowing of the requests) to expedite resolution. Plaintiffs goal throughout this entire process has been to come to some tentative agreement such that Defendants can begin the process of producing internal company documents. The remaining Requests requiring the Court’s attention at this time are discussed below by subject area.

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<sup>5</sup> Defendants attempted explanation of how it might construe the term “potential nitrosamine contamination” is circular. *See* ZHP Email to Counsel at Ex. 4 (“it is our view that the term “potential” as used in paragraph 6 [of the Court’s Order] refers to regulatory communications about an occurrence or incident that resulted in a potential or actual contamination or to unidentified peaks **in tests capable of detecting nitrosamines.**”) (emphasis added). By defining “potential” nitrosamine formation with respect to peaks in “tests capable of detecting nitrosamines,” Defendants have carefully defined the issue in a way that will ensure that no documents would meet this standard, as they have repeatedly suggested only after the worldwide recall was a test validated to detect nitrosamines.

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**1. Corporate Organization & Custodians (Request Nos. 1-4)**

The Parties have a dispute regarding Request. No. 2, which requests corporate officer, director, and ownership information. Defendants should be required to produce these documents for two reasons. First, this information is necessary so that Plaintiffs can clearly establish corporate governance, responsibilities, and lines of control given the interlocking nature of the various Defendants. This is particularly important with respect to the foreign entities, including those who have already appeared and those still awaiting service.<sup>6</sup> Second, the information is necessary for Plaintiffs to determine not only corporate control but also financial responsibilities and potential liabilities of the various Defendants for purposes of class certification. Plaintiffs do not want to end up in a position where, during briefing of class certification, Defendants point to purported defects in the class definition based upon a particular entity's lack of control or responsibility over a particular issue, because Plaintiffs have not been able to accurately determine each entities' structure and role in the manufacturing, regulatory, and distribution process.

**2. Policies and Procedures (Request No. 5)**

The Parties have no current disputes with respect to this category.

**3. Agreements (Request Nos. 6-9)**

While the Parties have no disputes pending with these requests, the Court's December 2, 2019 email expressed concern with Request Nos. 6, 8, and 9, which fall under this topic. Each of

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<sup>6</sup> While the Court's December 2, 2019 email guidance identified Request Nos. 3-4 as among those that should be narrowed, at this point in time the Parties have no fundamental disputes about what Defendants will produced as a result of these requests.

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these requests (as amended by Plaintiffs) seeks relevant, discoverable information that Defendants should be ordered to produce.

Request No. 6 is limited to agreements<sup>7</sup> relating to the specified areas pertaining to valsartan or its ingredients. The enunciated areas (e.g., manufacture, testing, etc.) all relate to core areas or topics at issue in this litigation. The requested agreements are relevant to show, for example, whether any Defendant contracted with any third party to manufacture valsartan API or finished dose on its behalf (e.g., agreements between a valsartan API manufacturer and a valsartan finished dose manufacturer); to test valsartan (including, e.g., testing for contamination), and other quality assurance functions.

Request No. 8 seeks documents related to retention of third parties. Core discovery suggests that one or more Defendants have retained third-party consultants to interact with the FDA about the valsartan contamination at issue in this litigation. Plaintiffs are entitled to discover the identities of such third-parties, and the scope of their assignment on behalf of any Defendant *vis-à-vis* valsartan API or finished dose. Not only do these documents bear upon factual issues related to the contamination, but they will also provide relevant information as to which entities should be subpoenaed.

Similar to Request No. 8, Request No. 9 bears upon whether any Defendant retained third parties to analyze the safety, bioequivalence, purity, or contamination, the identities of such persons, and the scope of their assignment on behalf of any Defendant *vis-à-vis* valsartan API or

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<sup>7</sup> To the Court's question as to what an "informal agreement" is, parties often agree to terms in emails or more informal documents, as opposed to formal, traditional contract forms. This term is merely meant to capture these types agreements in addition to formal contracts.

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finished dose. This discovery is relevant and likely to lead to admissible evidence. Indeed, for example, many of the Defendants retained outside toxicology experts to conduct analyses of NDMA and NDEA in the wake of the recalls. Plaintiffs are entitled to discover documents embodying the scope of their retention, what they were asked to analyze, the information upon which they had based their analysis, and how much these experts were compensated for their time in conducting the analysis.

**4. Intra-Defendant Communications (Request No. 10)**

While the Parties have no disputes pending with intra-defendant request, the Court's December 2, 2019 email expressed concern with Request No. 10 under this topic, which requests documents related to communications between Defendant related to valsartan.

Request No. 10 is essentially limited to intra-defendant communications about valsartan or its ingredients within the specific topic areas, all of which relate to the issues in this case. Some Defendants (e.g., Teva and Torrent) purchased valsartan API from other Defendants (e.g., Mylan and ZHP). Communications among these Defendants about the manufacture, testing, etc., of valsartan API is highly relevant. Indeed, Defendants will be producing their own internal documents about these subjects; there is no reason they should not also produce communications among themselves about these same subjects.

Additionally, Defendants have not articulated any basis why such communications should be shielded from discovery or provided any estimate on how many intra-defendant communications (if any) exist. Simply put, there is no reason for Defendants to withhold responsive, relevant communications between themselves about the core subjects of this litigation.

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**5. ANDA and DMF (Request Nos. 11-15)**

The Parties have an overarching dispute with respect to the Requests relating to ANDA and Drug Master File (“DMF”) about whether Defendants are required to produce documents relating to both approved and unapproved valsartan containing drugs (“VCDs”). Defendants represented on a December 3, 2019, meet-and-confer call that they have produced all DMFs for VCDs. Accordingly, Plaintiffs do not address Request No. 15 (which is limited to DMFs). Defendants have likewise represented that they have produced all ANDA documents related to VCDs that are both approved, and currently on the market, in the course of core discovery.

***a) Unapproved, Tentatively Approved, or Withdrawn ANDA Applications***

Request Nos. 11-14 relate to valsartan ANDA files and documents regarding those ANDA files. Defendants assert a number of specious objections to these obviously relevant requests that generally ask Defendants to produce complete valsartan ANDAs to the extent not already produced and documents relating to such ANDAs, correspondence with the FDA regarding valsartan ANDAs, and lists of valsartan ingredients submitted to regulatory authorities.

The Court should strike Defendants’ boilerplate objections that these requests are somehow wholly duplicative of core discovery, vague and ambiguous, unreasonably difficult to locate (which itself would be a violation of cGMPs, which require a manufacturer to have ANDA files centrally located), outside the possession custody or control of the defendant, or not relevant to the case. The Court should also reject Defendants’ other more specific objections to these requests.

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First, Defendants refuse to produce materials for valsartan ANDAs that were not ultimately approved (e.g., withdrawn, rejected, unapproved, or tentatively approved). For example, at a minimum, the Teva Defendants and Mylan Defendants have unapproved valsartan ANDAs that were either withdrawn or rejected, and ZHP has a tentatively approved ANDA for a VCD (valsartan nevivolol)<sup>8</sup> as well. Information concerning the manufacturing processes in these ANDAs, the potential for such Defendants to have been placed on actual or constructive notice of the contamination through these ANDAs, and obviously, the very reasons these ANDAs were withdrawn and/or have not been approved, are highly relevant to the litigation.<sup>9</sup> In addition, these files are simple to produce as the ANDA and DMF files themselves are centrally maintained, and search terms and custodial files can be agreed upon to target these particular

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<sup>8</sup> During the course of meet-and-confers which discussed the issue of the tentatively approved ANDAs, Counsel for ZHP claimed to be completely unaware that ZHP had filed an ANDA application for a valsartan neбиволol product (ANDA No. 210596), despite the fact that this ANDA application was the subject of a patent litigation (in which ZHP, Princeton and Solco were named Defendants) in 2017 before Honorable Martinotti in *this very district*. See 3:17-cv-07191-BRM-TJB (D.N.J.). The Parties stipulated to dismissal in January of 2019, months after the recalls began. What makes ANDA 210596 troubling is that nowhere in the DMF files for ZHP's Valsartan API process is there any reference to this particular ANDA application. While Plaintiffs want to accept Defendant ZHP's representation that ZHP only has two DMF files for Valsartan manufacture process, without the ANDA file for the Valsartan Nebivolol product, Plaintiffs are unable to confirm whether that is, in fact, the case.

<sup>9</sup> Mylan's ANDA 204743 for an amlodipine, valsartan hydrochlorothiazide product (which was initially submitted in 2012 to the FDA) has *still* not been approved by the FDA some 5 years later. Plaintiffs are entitled to know any and all issues the FDA observed with respect to Mylan's compliance with cGMPs, which has prevented the FDA from approving this specific VCD ANDA application for over 5 years. Plaintiffs are entitled to know what deficiencies the FDA observed with respect to Mylan's cGMP compliance, quality assurance functions, and testing at their finished dose facilities which prevented them from approving this ANDA application. Plaintiffs are also entitled to know why this particular ANDA has not be approved, when Mylan's other concomitantly filed ANDA applications were approved.

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ANDAs (e.g., by referencing the actual ANDA number as a search term) and custodians likely to have relevant documents.

The unfairness of Defendants' position can be highlighted by Aurolife's willingness to produce its own valsartan ANDA and DMF documents for a VCD that was not subject to the recall. Defendants cannot have it both ways, only producing this information for VCDs that they believe make them look better and withholding evidence for unapproved/withdrawn VCDs that may be damaging to Defendants' defenses in this case. In meet-and-confers, Defendants were unable to articulate the basis for their objection other than the fact that the valsartan under these ANDAs never was sold.

In fact, the Court's November 20 oral ruling provides significant guidance in this regard. The Court ruled that Plaintiffs could obtain discovery regarding non-contaminated API facilities and from all finished dose valsartan manufacturers because of the potential actual or constructive notice issues. *See* Nov. 20, 2019 Oral Ruling, at 13-15. The Court did not require a nexus that the facilities have sold recalled valsartan because even non-recalled valsartan could inform on liability issues such as actual or constructive notice or negligence per se. Here, the argument is even stronger because it's entirely possible that these unapproved/withdrawn ANDA products themselves were yielding contaminated product.

In a too little too late compromise offer, Defendants offered on December 3, 2019 to provide "API testing results, inspection reports, and communications regarding potential or actual nitrosamine contamination regardless of whether those categories of documents are contained in approved or unapproved applications." This is completely illusory. Defendants are already under an obligation to provide inspection reports detailing compliance (or non-

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compliance) of cGMP obligations for all valsartan facilities. And Defendants' counsel, again, refused to describe how Defendants define potential nitrosamine contamination.<sup>10</sup> Plaintiffs cannot agree to a compromise for documents that Defendants are already under an obligation to produce and/or that is not adequately described to them. Furthermore, Defendants are required to keep these ANDA files in consolidated in centralized locations pursuant to their obligations under cGMPs, so the burden to Defendants to produce these few unapproved, tentatively approved, or withdrawn products is minimal.

As such, the Court should order Defendants to fully respond to Request Nos. 11-14, and to produce that which Defendants were required to produce core discovery for these unapproved, tentatively approved, or withdrawn valsartan ANDAs.

**6. Document Retention/Destruction Policies (Request No. 16)**

All Defendants refuse to produce their document retention policies (or commit to a response that their companies do not maintain document retention policies) on the basis of relevancy and proportionality, and because they claim evidence of spoliation is a condition precedent to these policies' production. These objections are without merit. The Court should compel production of these policies.

***a) Defendants Ignore the Fact that Document Retention Policies Bear Upon cGMP Compliance***

Defendants' document retention and destruction policies (and/or the existence or non-existence of such policies), are evidence of Defendants' larger compliance (or non-compliance)

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<sup>10</sup> This issue is one that is pervasive throughout all sections of Defendants' responses to Plaintiffs' requests. As discussed *supra*, Defendants' circular definition of "potential" nitrosamine contamination is nonsensical, as it defines a "potential" nitrosamine contamination in terms of a peak on a test "capable of detecting nitrosamines." Ex. 4

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with cGMP practices and guidelines. Indeed, as per 21 CFR § 211.180, certain documents must be retained for at least 1 year after the expiration of a batch, must be readily available for authorized inspection, and must be retained as either original records or true copies. Documents which are required to be maintained under § 211 include (but are not limited to), standard operating procedures, specification, standards, sampling plans, test procedures, and other laboratory controls, and documentation of all complaints, deviation reports, OOS or OOT findings. Production of the document retention policies (or a response by any Defendant that they do not keep such or maintain document retention policies) bears directly upon a Defendant's compliance with their obligations under the federal regulations and cGMPs.

***b) Defendants Spoliation Objections Are Without Merit***

While Plaintiffs are fundamentally entitled to a response regarding document retention policies (either by their production, or by a response stating a Defendant does not keep or maintain document retention policies) to assess cGMP compliance, Plaintiffs would also be entitled to these documents for issues bearing upon spoliation.

Defendants are incorrect that evidence of spoliation must be antecedent to the production of document retention and destruction policies. The policies are prima facie discoverable without an initial showing of potential spoliation because such policies bear on the “existence...custody...and location of any documents or other tangible things.” *See In re Takata Airbags Prods. Liab. Litig.*, MDL No. 2599, 2017 WL 8812734, at \*5 (S.D. Fla. July 5, 2017) (Ex. 36) (quoting Fed. R. Civ. P. 26(b), advisory committee's note (2015)); *see also, e.g., Newman v. Borders*, 257 F.R.D. 1, 3 (D.D.C. 2009) (“That a party's document retention policies, including its policies as to electronically stored information, may be a fit subject of discovery

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cannot be gainsaid”). The Federal Rules do not establish a showing of spoliation as a condition precedent to retention policies’ discoverability. *In re Takata*, 2017WL 8812734, at \*5 (Ex. 36). Document retention policies are also relevant to demonstrate the reasonableness of Defendants’ discharging their obligation to search for and produce responsive documents. *See, e.g., Smith v. Life Investors Ins. Co. of Am.*, No. 2:07–cv–681, 2009 WL 2045197, at \*7 (W.D. Pa. July 9, 2009) (Ex. 37). Thus, there is little question that Defendants’ retention policies are relevant and discoverable now.

Even were Defendants correct that some threshold showing of spoliation was necessary – and they are not – such showings *do* exist here. *See, e.g., Ex. 5*, (2016 Form 483 to Hetero Labs Ltd.) (finding that a mere 4 days before an announced FDA inspection, Hetero employees were observed on CCTV footage engaging in “extensive shredding of ...controlled documents and extensive signing of documents by QA,” some of which occurring during the dead of night), *Ex. 6* (2017 Mylan Nashik Warning Ltr.) (finding that audit trails for tests indicated “deleted result set” or “project integrity failed” messages which went uninvestigated)(italics added); (*Ex. 7* (2017 Form 483 re Aurobindo) (finding that Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards”)).

The foregoing examples of deleted test results and surreptitious shredding more than justify production of Defendants’ document retention policies at this time.

Finally, as to Defendants’ objection of proportionality, no Defendant has made any showing that it would be unduly burdensome to produce their retention and destruction policies. This is hardly surprising, given that such policies should be within very specific, discrete

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documents. *Cf. In re Takata*, 2017 WL 8812734, at \*6 (noting it was not burdensome for defendants to produce 17 years' worth of document retention policies).

**7. Manufacturing (Request Nos. 19-29)**

During the course of the Parties' meet-and-confers over the past months, the Parties have made tremendous progress related to the Manufacturing requests.<sup>11</sup> Defendants, for their part, have committed to producing a set of key and critical documents related to their manufacturing functions. API Manufacturers have committed to producing, on an expedited basis, documents related to "(1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019." *See* Pls. Nov. 11, 2019 Ltr. attached at Ex. 1. Finished Dose Manufacturers (including API Defendants who manufactured finished dose as well), committed to producing documents in their possession related to any documents received from their API sources regarding the manufacturing process utilized for valsartan API (including any due diligence documents associated with the selection of the API source).

However, the Parties do still have a dispute about whether the API Defendants are required to produce a small subsection of manufacturing documents regarding the valsartan synthesis process development that relate to Request Nos. 19 and 20.

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<sup>11</sup> The Court only identified one request under this topic is potentially requiring revision, Request No. 27. This request, as narrowed, seeks highly relevant documents about two discrete areas: valsartan tracking data, and solvents.

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***a) Plaintiffs Are Entitled to Limited Production of API Synthesis Documents Pre-dating 2010***

Plaintiffs ask the Court to compel production of a limited subsection of documents related to the valsartan API chemical synthesis process development, and any changes made to that process, which pre-date the beginning of the Court's discovery limitations. These discrete documents include: change request reports related to the valsartan API manufacturing process, risk assessments related to the valsartan API manufacturing process, reports and analyses of the lab-scale development of the API manufacturing process, and deviation and/or "out of spec" or "out of trend" reports associated with any lab-scale development or manufacturing change process for the valsartan API synthesis.

During the Court's November 20, 2019 oral ruling, the Court stated that its discovery cut-off did not "foreclose plaintiffs from asking for earlier, discrete and identifiable categories of documents or individual documents." *See* Tr. of Court's Oral Ruling at 23:11-16. These documents regarding the development of the API process are precisely the types of "discrete and identifiable categories" of documents that bear directly upon the key issues of this case – the manufacturing process development, and what Defendants knew about the synthesis process, and when. For their part, Defendants have objected because Defendants argue that Plaintiffs' request does not satisfy the Court's requirement regarding specificity and cause, especially considering it was subject to the Court's November 25 ruling. *See* Ex. 4.

However, as Plaintiffs discussed in their earlier briefing to the Court (and during the meet-and-confer with Defendants), the initial development of the synthesis process for manufacturing valsartan API occurred prior to 2010 and 2011 for the Defendants ZHP and

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Mylan. With respect to Defendant ZHP, the product development of Valsartan API began as early as September of 2007, when ZHP filed a DMF with the FDA for their first valsartan synthesis process. *See* PRINSTON00078567. This chemical synthesis process would later go on to be known as Process I, and utilized a tin compound as its catalyst for the tetrazole ring formation. *Id.* After filing this first DMF application to the FDA, on January 1, 2010, ZHP filed a *second* application to the FDA for a *second* process for the manufacture of Valsartan, which would be known as Process II (which used the chemical compound Triethylamine (“TEA”)). *See* PRINSTON00073120. ZHP further modified Process II from 2011 to 2013, to change the tetrazole ring formation process from TEA to one that used Zinc Chloride and Dimethylformamide. Process II would later go on to be the process which resulted in the formation of NDMA and NDEA, while the earlier tin-based process (Process I) *did not* create nitrosamines. While the Court’s discovery timing would allow for documents regarding the process change made in 2011 from TEA to Zinc Chloride for Process II, it would exclude, in its entirety, any documentation created in assessing the change from Process I to Process II, which occurred between 2007 and 2009.<sup>12</sup> Plaintiffs must be afforded documents and analysis regarding this change, which Defendants are required to create (and maintain) as part of their cGMP requirements. *See* 21 CFR § 211.100(b) “[w]ritten production and process control procedures must be followed in the execution of the various **production and process control functions and must be documented at the time of performance.** Any deviation from the

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<sup>12</sup> Plaintiffs are aware that on November 27, 2011, ZHP initiated a “critical change request” for the stated purpose of “making changes to the [Process II] Valsartan manufacturing process.” *See* 2018 EIR. As such, Plaintiffs would expect that when making the change from Process I to Process II, ZHP initiated a similar “critical change request.”

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written procedures must be recorded and justified.”<sup>13</sup> Further, because they must be kept and made available as part of cGMP requirements, the documents should be organized and manageably produced without any undue burden.

**8. Bioequivalence (Request Nos. 30-34)**

Defendants continue to object to producing bioequivalence discovery despite the Court’s clear guidance at the November 20 CMC, and Defendants’ own statements that for certain types of testing documents, they intended to rely on the testing conducted as part of their bioequivalence studies. The Court stated the following:

As to bioequivalence testing, this testing is relevant to the master economic loss claims and whether the purchasers got what they paid for. The testing is also relevant to whether defendants were or should have been aware of quality control issues, thus, **bioequivalence testing shall be produced**. Disputes regarding what testing should be produced, if any, should be raised in time to be addressed at the December 11 conference.

(Nov. 20, 2019 Oral Ruling) at 22 (emphasis added).

Unbelievably, on the December 3 meet-and-confer call, Defendants continued to take the position that bioequivalence discovery is objectionable. Defendants were also completely unwilling to even engage in compromise positions. For example, with regard to Request No.

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<sup>13</sup> See, also, 21 CFR § 211.160(a), (“the establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, must be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. These requirements must be followed and documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms must be recorded and justified.”)

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34,<sup>14</sup> Plaintiffs proposed that Defendants produce complete ECF filings (and exhibits) for patent litigation (much of which proceeds under seal pursuant to a protective order). Defendants declined the invitation and claimed that even court filings and documents produced in discovery to opposing parties was somehow subject to claims of privilege. The Court should order Defendants to comply with the Court's already-expressed clear guidance that bioequivalence discovery is discoverable.

**9. Testing (Request Nos. 35-43)**

Request Nos. 35-43 seek documents relating to Defendants' testing of valsartan API and valsartan finished dose. Relatedly, the Court has already ordered Defendants to identify testing. Each of these issues – particular requests and compliance with the Court's November 25 Order – are addressed below and cut across all of the pertinent requests. ZHP is the only Defendant who has provided the testing data was required by the Court's order.

**a) *Plaintiffs Do Not Have Sufficient Information to Limit Testing Requests.***

This Court's Oral Ruling and subsequent Order dated November 25, 2019 largely clarified the scope of discovery to be produced concerning testing and the nitrosamines and contaminants contained within valsartan and solvents used to manufacture valsartan. The Court's Order required the parties to meet-and-confer prior to the December 11, 2019 case management conference such that disputes, if any, regarding what testing should be produced could be addressed at the December 11 conference. To facilitate this discussion, the Court held

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<sup>14</sup> Request No. 34 asked for "Documentation of any patent litigation between you and either the Brand Manufacturer of the RLD regarding valsartan, or other generic companies which had filed an ANDA application for a valsartan product."

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that “testing results regarding other carcinogens, general toxic impurities or residual solvents in the Valsartan is relevant” and further directed the Defendants to “identify the types and purposes of the tests done on Valsartan API and Valsartan” prior to the December 11 conference.

Rather than produce a simple list in letter format identifying “the types and purposes of the tests,” Plaintiffs received a December 2, 2019 letter from counsel for ZHP<sup>15</sup> that identified 33 documents produced in core discovery, spanning scores of pages, from which ZHP’s counsel suggest Plaintiffs could root out “[t]he types of testing performed during the valsartan API and finished dose manufacturing processes. . . .” *See* Ex. 8. ZHP’s hide-the-ball response does not comport with the Court’s Order.

First, on its face, ZHP’s response does not comply with the Court’s order in that it fails to identify the “types and purposes” of the testing performed. It merely identifies Bates numbers from which ZHP essentially suggest Plaintiffs should review to identify on their own the types and purposes of the testing.<sup>16</sup>

Second, ZHP’s response significantly frustrates the meet-and-confer process. Assuming all other API and finished dose manufacturers follow ZHP’s suit, Plaintiffs would be required to comb through hundreds of pages of documents in connection with their experts and compile their own list of what testing Plaintiffs believe the documents show for each manufacturer. This

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<sup>15</sup> As of the date of this filing, aside from ZHP’s response, no other defendant has complied with its obligation to produce any information, either by citing to documents, or producing a list of tests.

<sup>16</sup> It is also worth noting that had Defendants provided Plaintiffs with the documents given to the FDA during inspections of their facilities, Plaintiffs would have a better understanding of the types of tests which were demonstrating OOS or OOT results. However, because Defendants have only recently committed to producing these documents (but have not committed to a date by which they would produce these documents), Plaintiffs’ hands are tied in many respects.

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process would likely take many weeks and would require completion prior to any meet-and-confer. This process could not be completed prior to December 11, 2019, and certainly not before the December 5, 2019 simultaneous briefs are filed. The Court's order did not contemplate such a protracted process

Third, even if Plaintiffs were to partake in the process suggested by ZHP, Plaintiffs would be left to wonder whether they had indeed correctly identified all the types and purposes of the testing reflected in the hundreds of pages of documents that require searching without specific confirmation from Defendants.

Based upon its December 2, 2019 letter, it is abundantly clear that ZHP and its counsel know exactly the types and the purposes of all of the testing performed on the valsartan it manufactures. While Plaintiffs are appreciative of the exemplar documents ZHP has provided of various tests, Plaintiffs believe that in the overwhelming interest of efficiency, ZHP and all other Defendants must be required to identify in letter form the specific name and purpose of all types of testing performed as per the direction of the Court.

**10. Nitrosamines and Contamination (Request Nos. 44-50)**

Similar to the issue regarding the testing requests, Plaintiffs do not have enough information at this point in time to further narrow their requests regarding Nitrosamine Contamination (Request Nos. 44-50). These requests are intricately linked to the matter of testing addressed above, *viz.*, what nitrosamines and contamination did or may have existed, about which each Defendant knew or should have known. Nevertheless, in the abundance of clarity, Plaintiffs would ask the Court to compel production of documents responsive to these

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requests (to the extent they exist) for other nitrosamine contaminations (such as, for example, DIPNA, EIPNA and NMBA).

**a) *Documents Regarding all Nitrosamine Contamination including DIPNA, EIPNA and NMBA***

The Court has previously held that Plaintiffs are not entitled to discovery regarding other sartan products, but never made any such limitations with respect to documents regarding other nitrosamine impurities. Documents detailing the testing results for DIPNA, EIPNA and NMBA would inform upon the NDMA and NDEA testing results. Furthermore, Defendants did test their API products for these impurities.<sup>17</sup>

**11. Regulatory Correspondence and Documents (Request Nos. 51-64)**

While the Parties are largely in agreement regarding production of regulatory correspondence and documents, two larger issues still remain with respect to production of regulatory correspondence documents.

**a) *Correspondence with Foreign Regulatory Agencies Regarding “Potential Nitrosamine Contamination”***

Request Nos. 51-54 seek regulatory documents regarding the recall of valsartan. At issue between the Parties is whether Defendants will produce documents from foreign regulatory agencies pursuant to these requests.

As per the Court’s ruling, Plaintiffs are entitled to “communications regarding potential or actual nitrosamine contamination” that occurred prior to the July 2018 recall. *See* Tr. at

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<sup>17</sup> [https://www.ema.europa.eu/en/documents/referral/sartans-article-31-referral-chmp-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/referral/sartans-article-31-referral-chmp-assessment-report_en.pdf) (last accessed December 5, 2019) (finding that ten valsartan API batches from a manufacturer have been tested with a validated GC-MS for the simultaneous detection of NDMA, NDEA, NDIPA and NIPEA)

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20:16-23. During the Parties' November 26, 2019, meet-and-confer, Plaintiffs asked Defendants for clarification on whether they would produce foreign regulatory agency documents related to "potential" nitrosamine contamination to the extent the communications occurred prior to July 2018, and how Defendants would construe the term "potential" nitrosamine contamination. Defendants responded that they construe the term to mean "communications about an occurrence or incident that resulted in a potential or actual contamination or to unidentified peaks in tests capable of detecting nitrosamines." As discussed, this definition is a circular argument. Defendants are the ones with control over their own documents. They are in the best position to explain what types of "potential" contamination their documents reveal was (or should have been) detected. This certainly may include "unidentified peaks," but that alone is not and cannot be the sole type of "potential" contamination signal that Defendants must produce. The Court meant what it said – documents about "actual" or "potential" nitrosamine contamination must be produced. Defendants cannot unilaterally limit the Court's clear guideline to only one type of "potential" contamination, and further define that "potential" contamination in terms of a test ("tests capable of detecting nitrosamines") which they themselves further refuse to define, or have repeatedly stated was not in existence prior to the recall.

**b) *Regulatory Communications Regarding Unapproved, Tentatively Approved or Withdrawn ANDAs***

Plaintiffs are entitled to communications with the FDA regarding unapproved, tentatively approved or withdrawn ANDA applications. Such documents are responsive to Request Nos. 52-54. However, Defendants have taken the position that these documents should only be produced to the extent they discuss nitrosamine contamination. The real issue here is that an

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unapproved or withdrawn ANDA will reveal *how* a Defendant *proposed* to manufacture valsartan, and test that valsartan, in ways that it *did not* do for its contaminated valsartan in this case. Furthermore, in their generic advice letter, the FDA wrote to “pending” application holders of ARB drugs and delineated “recommended actions to take that ensure your drug product, drug substance/active pharmaceutical ingredient (API) and raw materials” are absent of nitrosamine impurities. *See* Ex. 9, General Advice to Pending Applicants. Plaintiffs must be afforded the opportunity to compare the various statements Defendants made with respect to their ANDA applications, regardless of whether the application was approved, or pending.

**c) Documents Regarding cGMP Compliance**

The Court’s December 2 email only flagged Request No. 65, which discussed compliance with cGMPs, as one meriting potential discussion.

Defendants are required to maintain protocols and records concerning their efforts to comply with cGMPs, which touch on things like testing procedures; analysis of testing; retention of testing records; and much more. Indeed, Defendants appear to have whole quality assurance or regulatory departments staffed with personnel whose principal responsibilities are to ensure cGMP compliance. These key documents bear on Defendants’ practices with respect to the manufacture of valsartan API or valsartan finished dose. The core discovery produced to date includes numerous Form 483s and Warning Letters informing each Defendant of cGMP violations at their manufacturing facilities that make valsartan API or finished dose.<sup>18</sup> The violations – both those specific to valsartan (e.g., test results for valsartan not being retained) or

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<sup>18</sup> Plaintiffs simply note they have not received inspection reports regarding the finished dose facilities utilized by the API Manufacturer Defendants, although these API Manufacturer Defendants have indicated production is forthcoming.

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more generally (e.g., general failure to maintain proper quality assurance testing and logs) – are directly relevant to Plaintiffs’ claims that Defendants knew or should have known of the risk of valsartan contamination.

Further, Plaintiffs have learned that at least one of more Defendants have retained third-party consultants to address cGMP failures identified by the FDA at Defendants’ facilities that manufacture valsartan API or finished dose. What hired guns told the FDA about cGMP violations, on behalf of Defendants, is just as important as what Defendants might have told the FDA directly.

## **12. Complaints and Recalls (Request Nos. 66-78)**

The parties met and conferred on requests related to complaints and recalls and have come to agreement on most requests. However, two outstanding issues still remain. Pursuant to that discussion, the parties have agreed that most objections were resolved by the Court’s ruling on the Macro Discovery issues. It is therefore Plaintiffs’ understanding that any objections not addressed in this Memorandum was resolved by the order and will not be used to withhold additional documents.<sup>19</sup>

### ***a) Complaint and Recall Documents Relating to both Valsartan API and Valsartan Finished Dose***

Throughout their objections to these requests, Defendants repeatedly objected to the definition of Valsartan (which necessarily includes API and finished dose formulation) and have taken the position that Plaintiffs are *only* entitled to responsive documents regarding complaints and recalls related to the Valsartan API (and not finished dose). However, in drafting the

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<sup>19</sup> To the extent Plaintiffs are incorrect, they will address this in their reply brief.

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definition of “Valsartan,” Plaintiffs intended for it to take on a broad meaning, encompassing both the API, as well as the finished product. Indeed, this is because obligations to promptly attach not only for the manufacturer of the API, but also the manufacturer of the finished dose. Indeed, it is the ANDA holders of valsartan finished dose (and not the DMF holders of Valsartan API) who are under affirmative obligation pursuant to field alert report (“FARs”) regulations found in 21 CFR § 314.81(b)(1) and § 314.98(b). These obligations include establishing an early warning system to help protect patient health. *See* 21 CFR § 314.81(b)(1) and § 314.98(b). The regulations also require the ANDA holders to affirmatively submit a FAR to the FDA within 3 working days after receiving information related to “any significant chemical...change in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it” in the ANDA application. *Id.*

Consequently, documents related to complaints and recalls associated with the finished dose products are precisely the types of documents Plaintiffs would expect to be responsive to Request Nos. 66 to 78. The ANDA applicants are the entities who are allowed to market in the United States, and the ANDA applications cover the finished dose products. As such the ANDA applicant is the entity responsible for the recall of their finished dose product, and the entity responsible for communicating information regarding the recall to pharmacies, consumers, and physicians. In making a unilateral determination that they are only required to complaints and recall related documents associated with the API manufacturing, Defendants are so narrowing the request that they actually would be required to produce almost no documents.

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***b) Defendants Must Be Required to Produce Documents to the Extent they are within their Control***

A number of Defendants objected to RFPDs, noting that the requested documents may be outside of their possession, custody, or control. However, the standard for “possession, custody, or control” is well defined under New Jersey law. In the District of New Jersey “control” is liberally construed and relies on whether the corporate relationships “establishes some legal right, authority or ability to obtain the requested documents on demand.” (emphasis original) *Camden Iron & Metal, Inc. v. Marubeni Am. Corp.*, 138 F.R.D. 438, 442 (D.N.J. 1991). Understanding that this issue is well defined under the law, Plaintiffs ask that this objection be stricken and not used to withhold any documents which are in the possession, custody, or control of any defendant.

***c) Defendants Must Be Required Produce Communications Made to Physicians***

Request No. 70 requires production of “all communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.” Defendants will not commit to producing such communications. However, communications with physicians will demonstrate whether Defendants made any representations and/or warranties regarding the safety, purity, bioequivalence, and/or contamination regarding the VCDs at issue in this case. These statements will be critical to proving Plaintiffs’ claims regarding warranty issues and thus should not be limited. Moreover, this request will show the Defendants’ states of mind in how they handled the recall. Defendants should thus be compelled to respond to it in full, particularly in light of the fact that they failed to articulate any basis for withholding documents during the meet-and-confer process.

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**13. Warranties and Statements (Request Nos. 79-92)**

Plaintiffs have withdrawn Request No. 82, the only request in this section that the Court had flagged in its December 2, 2019, email. As to the other requests highlighted herein, Defendants have failed to demonstrate why they should not be required to respond to these requests and instead have chosen to hide behind improper objections.

**a) *Documents Regarding Communications to Investors Related to Manufacturing Processes and Facilities***

Requests No. 85 and 87 both concern statements made to investors relating to the quality, purity, contamination, safety, or manufacturing processes. Defendants have objected and/or referred Plaintiffs to publicly available sources. First, many of the statements made to investors and/or shareholders are not publicly available. Shareholders are often provided information through confidential phone calls, meetings, or other forms of communications which are not available to the public. Additionally, these statements will shed light on representations made about all of the topics listed, as well as on how the companies portrayed the severity of the contamination before, during, and after the recalls. Additionally, there is evidence to suggest that some Defendants made pejorative statements regarding Chinese and Indian pharmaceutical manufacturers. Indeed, Teva's President and CEO made comments while participating in the European Association of Pharmaceutical Full-line Wholesalers conference that the prices of Indian and Chinese drug companies charged for the products demonstrated that these manufacturers were "cutting corners" and consumers would never "sit on a plane if [they] thought the parts were coming from a dodgy factor somewhere" and wondering "[s]o why do we accept this for medicines?" Ex. 10 (Article from Business Standard). These comments made by

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the Teva CEO were further responded to by Mylan Pharmaceuticals CEO Robert Coury, in the context of rejecting an unsolicited expression of interest. *See* Ex. 11, (Coury Letter to Teva).<sup>20</sup> As such, it is clear some Defendants (especially Defendants Mylan and Teva) were engaging in some discussion with investors regarding their foreign manufacturing and would have likely made statements or comments regarding the impact of the recall on their quarterly or yearly earnings. Thus, Defendants should be compelled to produce all documents responsive to these requests.

**b) *Documents and Communications with the NIH and WHO***

Plaintiffs requested documents and communications related to the valsartan contamination with a variety of organizations, including the National Institute of Health (“NIH”) and the World Health Organization (“WHO”) in Request No. 90. For their part, Defendants objected, indicating that all documents should be confined only to the US agencies. Some Defendants went as far as to indicate they would not produce documents relating to the WHO or NIH. *See, e.g.,* Aurobindo Amended Responses, RFP 90. These responses artificially limit responsive documents and are a fundamental misconstruction of the Court’s ruling on Macro Discovery. First, the NIH is a *US government organization*. Any insinuation that these documents would not already be limited to the United States is therefore baseless. While the WHO is headquartered outside the United States, it has a large presence within the country and has also been updating the public, including U.S. physicians, regarding the news regarding

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<sup>20</sup> “Teva ... been disparaging about India's products and culture...Bringing Teva's "dysfunctional" culture to the region could disrupt the core of our business, result in the flight of key talent (in India and elsewhere), and meaningfully and adversely impact the results of the possible combination.”

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nitrosamine impurities found in valsartan.<sup>21</sup> For this reason, communications with the WHO from any Defendant are relevant in that they can shed light on the manner in which information was (or was not) shared with important personnel, who in turn supply information to physicians who prescribe valsartan to patients like Plaintiffs. Defendants should thus be compelled to respond fully to this request.<sup>22</sup>

**14. Sales and Distribution (Request Nos. 93-98)**

At the Court's instruction, Plaintiffs substantially narrowed the scope of the sales and distribution documents. Nonetheless, Defendants maintain their objections, leaving Plaintiffs no choice but to raise these issues with the Court. As shown in the attached amended requests, Plaintiffs narrowed the scope of these requests.<sup>23</sup>

**a) *API Sourcing Due Diligence Documents***

Request Nos. 96 and 98 seek information on the due diligence conducted by finished dose defendants on API defendants. In order to further narrow the requests, Plaintiffs further clarified that this request only needed to be responded to by manufacturer entities which were not part of a vertically integrated chain, or in other words, only by manufacturers who were permitted to source API from other companies, not just the parent corporation. Similarly,

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<sup>21</sup> See e.g., [https://www.who.int/medicines/publications/drugalerts/InformationNote\\_Nitrosamine-impurities/en/](https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en/).

<sup>22</sup> In the interest of clarity, Plaintiffs would also ask that Defendant Aurobindo be required to produce whatever the Court orders appropriate for all other Defendants. For some subsection of these requests, Aurobindo's position is out of line with the other Defendants, and Aurobindo has provided no basis for why they must be treated any differently.

<sup>23</sup> For example, as to Requests 93-95, Plaintiffs indicated that if Defendants could find a way to respond to these requests in the form of an interrogatory response, Plaintiffs would be amenable to a proposal by Defendants to respond to the request in the form of an interrogatory response. Defendants indicated that they were considering this option but have not yet responded.

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Request No. 97 seeks information also aimed at shedding light on the information provided by API defendants to finished dose manufacturers. These requests will allow plaintiffs to understand what knowledge was shared among the API and finished dose manufacturer defendants and what measures were undertaken by finished dose defendants to ensure they were providing safe, pure, and bioequivalent products to consumers like Plaintiffs. Nonetheless, Defendants have refused to respond as to whether they will produce documents in response. Plaintiffs therefore ask that the Court compel production of documents and responses to the requests in this subsection under the present limitations proposed by Plaintiffs.

**15. Valsartan Purchasers, Sales, and Pricing (Request Nos. 99-106)**

Request Nos. 99-106 seek two general categories of documents: (a) regular documents (e.g., emails, presentations, etc.) concerning purchases, sales, and pricing for Defendants' valsartan products, and (b) transactional data reflecting the same.

***a) Pricing Business Documents Maintained in the Ordinary Course of Business***

Plaintiffs made straightforward requests for regular documents, such as presentations, excel spreadsheet, analyses, and the like, regarding valsartan purchasers, sales and pricing.<sup>24</sup> Nevertheless, Defendants' counsel claimed not to understand many of the requests, and during a November 14, 2019, meet-and-confer, Plaintiffs agreed to provide certain example documents for some of these requests. Those examples were provided to Defendants by a letter dated November 22 (attached as Ex. 2) that contained extensive lists of example documents for Request Nos. 102, 103, 104, 105, 109, and 110. That letter remains unanswered. Plaintiffs also

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<sup>24</sup> Request Nos. 99-101, 103-105

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added more detail when they amended these Requests. But, on a follow-up meet-and-confer on December 3, Defendants maintained their objections.

These requests seek specific types of ordinary-course sales, planning, forecasting, and contract documents. Such documents go, among other things, to the price differential for Defendants' contaminated valsartan as compared to non-party non-contaminated valsartan in the marketplace. Whether Defendants' contaminated valsartan was cheaper than competing non-contaminated valsartan is probative of the corners cut by Defendants in using recycled solvents or short-cut processes that led to the creation nitrosamines.

More fundamentally, contract and pricing documents (as opposed to data) are pertinent to identification of purchasers of Defendants' valsartan API and finished dose products, and damages.

***b) Transactional Data Kept in the Ordinary Course of Business***

In Request Nos. 106 and 120, Plaintiffs requested transactional data related to the sales and pricing of Valsartan. During a November 14 meet-and-confer, Defendants agreed to go back to their clients, consult with them about what data Defendants had and to propose a compromise as to what Defendants would be willing to produce. However, on the December 3, 2019, Defense Counsel admitted they have not met that commitment, and at that time, were unable or unwilling to identify *any*. Accordingly, Defendants were not prepared to meet-and-confer and simply demanded that Plaintiffs refine their requests without meaningful participation on their part for the more than a month of meet-and-confers.

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As things currently stand, Defendants incredulously object to producing *any* of the requested data on the basis of relevance. They further expect Plaintiffs to somehow narrow their list of data fields requested, without knowing what data fields each Defendant keeps.

The Parties and the Court do not need to re-invent the wheel here. Production of transactional data is routine in complex class actions cases. The data are obviously needed to show who purchased Defendants' valsartan API or valsartan finished dose products, when, and at what price. This information is relevant to several issues for class certification in the economic loss case, including numerosity, ascertainability, and damages. Plaintiffs need to know to whom Defendants sold valsartan API or finished dose, so Plaintiffs can trace (on a lot, batch, or other basis), which end-users purchased what drugs, that originated from which Defendant. Plaintiffs need pricing data fields so that their damages experts can opine on class-wide damages. Just because Defendants did not directly sell to consumers does not mean their sales data is irrelevant. For one, Plaintiffs bring claims under various state laws that permit remedies of restitution, disgorgement of profits, and unjust enrichment. Those remedies are directly based on Defendants' ill-gotten gains on their own sales or profits, regardless of further downstream transactions. Additionally, Defendants at different levels of the distribution chain may raise myriad defenses at class certification, such as offsets or pass-through defense. Without data for every single transaction in the chain – from Defendants to distributors to retailers to consumers – Plaintiffs cannot accurately test such defenses.

Defendants should be ordered to produce the requested data. At a minimum, Defendants should be ordered to tell Plaintiffs what data they possess (e.g., data fields, data dictionaries, field keys, columns, etc.), so the Parties can meaningfully confer about which data fields may or

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may not need to be produced. Plaintiffs cannot be expected to delineate data sources in a vacuum.

**16. Available Third-Party Data Sources**

Request Numbers 112 and 113 seek third-party data sources Defendants may have used to track quantities and prices of valsartan sold in the United States.

**a) *Commercially Available Data***

While the Court's December 2 email flagged Request No. 113 (which asked for commercially available data typically kept by pharmaceutical companies, such as IQVIA or IMS data), there is very little actually in dispute with respect to these requests. ZHP, Aurobindo, Teva, and Torrent have agreed to produce responsive non-privileged documents. Mylan is the outlier. Mylan refuses to produce anything, claiming only that it is willing to meet-and-confer further with Plaintiffs. This non-response should be stricken and they should produce responsive, non-privileged documents just like the other Defendants. The relevance of these documents is obvious: drug manufacturers and distributors regularly purchase prescription-level data (e.g., numbers of prescriptions; average sales price; market share; etc.) from one or more third-party sources that aggregate such data. *See generally IMS Health Inc. v. Sorrell*, 630 F.3d 263, 267 (2d Cir. 2010). Experts on both sides often use this data in rendering their opinions. *See, e.g., Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1331-32 (M.D. Fla. 2015) (noting plaintiff expert used same IMS data used by defendant in ordinary course of business). Plaintiffs are entitled to the documents or information Defendants use in tracking sales of valsartan in the United States. Mylan should be ordered to produce the requested documents.

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**b) *Copay Coupon Related Documents***

Request No. 114 ask for production of “all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.” Drug companies sometimes offer coupons or co-pay assistance to consumers who purchase their drugs to partially reduce the drug’s purchase price. Such documents are directly relevant to the amount or quantification of damages. Defendants’ objections and responses to this simple request are all over the map.

Torrent states it will produce any responsive non-privileged documents. Teva states the same, but only if located in custodians’ files. This is insufficient. If Teva maintains coupon or co-pay assistance information in non-custodial sources (e.g., databases, departmental files), it should be produced. There is no basis, and Teva articulates none, for limiting its response to this request to custodial files only.

ZHP and Aurobindo responded that they will produce responsive documents only about “reimbursements [ZHP or Aurobindo] offered to consumers because of the presence of NDMA or NDEA in valsartan.” While such documents would be responsive, they are only half the picture. If ZHP or Aurobindo (or any other Defendants) offered coupons or co-pay assistance to purchasers of valsartan in the ordinary course (and not just in the context of the recalls), such information is highly relevant, or at least discoverable, for purposes of damages calculations in the economic loss case. Or, if Defendants refuse to produce this information (if any), Defendants should be precluded from arguing at class certification that they are entitled to any offsets on account of non-produced information about coupons or co-pay assistance.

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Finally, Mylan claims it is not presently aware of any responsive materials. Mylan can not produce documents that do not exist. Nevertheless, if it does identify responsive documents to this request in the future, it should produce them just as other Defendants.

**17. Defendant-Specific Requests**

The Parties have no current disputes regarding any Defendant-specific requests that would not otherwise be subsumed in the above discussed disputes.

**B. Custodians**

Parties commonly negotiate a list of custodians from whose files responsive documents will be produced. *Carlin v. DairyAmerica, Inc.*, 978 F. Supp. 2d 1103, 1120 (E.D. Cal. 2013) (noting that disputes over custodians are “the sort of evidentiary conflicts normally negotiated during discovery”); *Romero v. Allstate Ins. Co.*, 271 F.R.D. 96, 109 (E.D. Pa. 2010) (“Among the items about which the court expects counsel to reach practical agreement without the court having to micro-manage e-discovery are search terms, date ranges, key players and the like.”) (quotation omitted); *The Sedona Conference, The Sedona Principles: Best Practices, Recommendations & Principles for Addressing Electronic Document Production*, Principle 3 (2d ed. June 2007) (“the Sedona Principles”); see also Sedona Principles cmt. 7(b) (“The intent of the Advisory Committee was that parties issuing and responding to subpoenas would avail themselves of [the opportunity to confer on a discovery plan] informally, a best practice that should be followed in most cases.”). This collaborative approach has the benefit of ensuring that the requesting party reasonably receives responsive documents from likely sources, while protecting the producing party from searching the files of all custodians, such as those highly

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unlikely to possess responsive documents. *See The Sedona Principles*, Principle 3 and comments thereto.

While some progress has been made on ESI custodians, disagreements on the identities of Defendants' first-round ESI custodians remains as follows for each Defendant:

**1. ZHP/Huhai US/Solco/Prinston**

Plaintiffs have limited information regarding many of the proposed custodians for ZHP, Huahai US, Prinston, and Solco (collectively, the "ZHP Defendants").<sup>25</sup> The ZHP Defendants have provided the bare minimum of information, even in response to the Court's explicit directions. ZHP's systematic obstruction of this process is exemplified by the fact that at the outset ZHP confidently told the Court that the eight custodians they originally disclosed were sufficient.<sup>26</sup> Plaintiffs request an Order adopting the proposed list of ZHP Defendants' custodians set forth in Ex. 12.<sup>27</sup>

Unlike in *Benicar*, a far less complex litigation according to the Defendants, where the plaintiffs had obtained a substantial volume of relevant documents through state court discovery before the formation of the MDL, Plaintiffs here have very limited knowledge. The current knowledge base comes from independent investigation and the Core Discovery, which does not

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<sup>25</sup> The ZHP Defendants also own either the entirety or the majority of two other significant non-parties; Shanghai Syncores Technologies, Inc., which helped develop the API manufacturing process for Valsartan, and Prinbury BioPharm Ltd., which helped develop the finished-dose manufacturing process for Valsartan. ZHP agrees that Plaintiffs may select custodians from these non-parties for purposes of ESI.

<sup>26</sup> A common refrain from ZHP's counsel is how difficult it is to get information from ZHP in China. However, ZHP's counsel has an office in Shanghai, and as noted below, Plaintiffs requested ZHP's organization charts in anticipation of this meet-and-confer months ago, in August.

<sup>27</sup> Plaintiffs have noted if ZHP has agreed to or disputed each custodian. If there is no response indicated from ZHP, the date of proffer by Plaintiffs is noted.

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include internal documents, email distribution lists, and key email and document authors and recipients. This leaves Plaintiffs at a tremendous disadvantage, which the Court has witnessed firsthand. The ZHP Defendants are thus in a commanding position when it comes to knowledge of custodians and search terms. As a result, it would be unfair to ask Plaintiffs to delete custodians who are necessary on their face, without a robust, substantive explanation establishing why each is not needed.

ZHP's obstruction is well illustrated by their ongoing refusal to agree that Jun Du is a proper custodian. Jun Du attended and acted as ZHP's point person for the key five-day 2018 Chuannan inspection by the FDA. The documents we have to date clearly establish that he should be included. Yet, in their November 27, 2019 letter, ZHP's counsel stated in part: "[h]is high-level view of the manufacturing process and testing at issue in this case is not the quality of key information possessed by the custodians that the ZHP Defendants have already proposed." (Ex. 13). This reasoning misses the point. This is a custodian who had direct involvement with the Valsartan contamination issue, and his custodial production will likely yield relevant, probative documents. The test certainly is not whether a particular custodian may have more or less "key information" than others. As we know, a small number of documents or even a single key document can be pivotal. ZHP's position with regard to Jun Du colors ZHP's entire position here, demonstrating a lack of understanding of the purpose of this process.

Rather than work cooperatively to provide information and assist Plaintiffs in establishing a reliable list of custodians, ZHP has consistently provided the minimum required, or less. In another illustrative example, on December 2, 2019 ZHP advised that it was refusing to provide translations of corporate organization charts it had just produced (Ex. 14), despite a

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Court Order directing that this be done. (Ex. 15). Plaintiffs request an explicit Order from the Court to correct this flagrant violation.

The ZHP Defendants have also told Plaintiffs that they must agree to an arbitrary maximum number of 50 custodians and have refused to engage in meaningful discussions regarding potential custodians unless and until Plaintiffs agree to the 50 custodian maximum. Most recently, on December 4, 2019, during a meet-and-confer that Plaintiffs insisted go forward, the ZHP Defendants reiterated this request and refused to tell Plaintiffs what work their proposed custodians had done on Valsartan, unless the custodian did not work on Valsartan at all. The custodian list cannot be limited to an arbitrary maximum number. Courts recognize that no arbitrary limit on the number of custodians should be imposed. Rather, the determination is based on the facts and theories of each case, and on a defendant's own business practices. There certainly is no authority for arbitrary limitation of the number of custodians, especially in a litigation of this complexity. *See, e.g., American Municipal Power, Inc. v. Voith Hydro, Inc.*, Civ. No. 2:17-cv-708, 2019 WL 6251339, at \*12 (S.D. Ohio Nov. 22, 2019) (Ex. 16) (190 custodians); *United States ex rel. McBride v. Halliburton Co.*, 272 F.R.D. 235, 236, 239-41 (D.D.C. 2011) (230 custodians). The question is which custodians should be searched to ensure the identification and production of the relevant, probative documents.

The chronology leading to this point is illustrative as well, and the demonstrated lack of cooperation to date should militate against arbitrary removal of proposed custodians. On August 14, 2019, Plaintiffs requested that the ZHP Defendants produce organization charts to further the meet-and-confer process regarding custodians. Ex. 17. On September 23, 2019, the ZHP Defendants provided Plaintiffs with a list of eight proposed custodians – which they stated was a

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fully adequate list, while failing to provide any corporate organization charts to help Plaintiffs evaluate this proposal. Ex. 18. In anticipation of the October 7, 2019 in-person meet-and-confer, Plaintiffs wrote to the Defendants on October 3, 2019, repeating the request for Defendants' organization charts. Ex. 19. At the October 7, 2019 meet-and-confer, the ZHP Defendants again failed to provide corporate organization charts. *See* Ex. 20 at p. 2.

On October 8, 2019, Plaintiffs sent the ZHP Defendants a list of seventeen additional proposed custodians. Ex. 21. The ZHP Defendants did not respond to this list. On October 9, 2019, Plaintiffs notified the Court of the refusal by the ZHP Defendants to meaningfully engage in the meet-and-confer process to identify the necessary custodians. Ex. 20. In response, the Court ordered Jun Du – who is a senior executive at ZHP, Huahai US, Princeton, and Solco as well as at Shanghai Syncores and Prinbury – to meet with Plaintiffs in person to discuss corporate organization, custodians, and search terms on October 23, 2019. Ex. 22. The Court also ordered that, “ZHP shall produce relevant corporate and business unit organization charts and directories **that will assist the parties to identify relevant records custodians and search terms.**” *Id.* The obvious import of the Order was that the organization charts would be translated in order to be of use.

After an October 16, 2019 meet-and-confer, the ZHP Defendants agreed to add thirteen custodians from the October 8, 2019 list, but still produced no organization charts. *See* Ex. 23 at 2-3. At 8:14 p.m. on October 22, 2019, the night before the Court-ordered meeting with Mr. Du, ZHP emailed five organization charts in the Chinese language from 2018 and 2019.<sup>28</sup> The timing of production, and Chinese language in these charts hampered Plaintiffs' effort to identify

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<sup>28</sup> The lack of corporate organization charts from earlier years remains a problem.

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necessary custodians. ZHP provided partial verbal translations of these charts during the meeting with Mr. Du, but also said that it would provide Plaintiffs with written translations.

On November 7, 2019, the Court ordered that Plaintiffs serve their preliminary custodian lists, and that the Defendants serve their translated organization charts, by November 15, 2019. Ex. 24. On November 13, 2019, ZHP produced **partial** translations of certain organization charts. Ex. 25. Plaintiffs served the preliminary list as ordered, and on November 14, 2019, the ZHP Defendants, despite admitting that they had “not had an opportunity to fully evaluate Plaintiffs’ entire list,” indicated that “a preliminary review reveals that Plaintiffs’ proposed list is wildly overly broad and unduly burdensome.” Ex. 26.

ZHP’s unhelpful approach continued on November 18, 2019 during a telephonic meet-and-confer. The ZHP Defendants’ counsel inexplicably began the meet-and-confer by insisting that Plaintiffs explain why they withdrew twenty-two custodians on November 22, 2019. Plaintiffs instead focused the discussion on the potential custodians still at issue. Unfortunately, ZHP’s counsel then proceeded to reiterate sweeping objections rather than engage in a focused factual discussion regarding the potential custodians. For example, ZHP’s counsel arbitrarily argued that Plaintiffs should remove eight of the sixteen custodians who attended the important May 19, 2017 close-out meeting with the FDA, during which the attendees discussed the FDA’s three major criticisms:

- 1- Appropriate controls are not implemented over Quality Control instruments to ensure the integrity of analytical testing. Furthermore, anomalies in analytical testing are not investigated.
- 2- Facilities and equipment are not maintained to ensure quality attributes of drug product.

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3- Invalidation of out-of-specification results lacks adequate scientific justification.

Ex. 27. ZHP was not willing to have a substantive discussion regarding each proposed custodian, ignoring the fact that they had different job titles and different reasons to attend the meeting, and offering no assurance that their probative custodial documents would all surface regardless of who was searched. When Plaintiffs asked ZHP's counsel to demonstrate that any two proposed custodians who attended the May 19, 2017 meeting were substantively duplicative of one another and why, ZHP refused to do so – likely because they could not support their obstructive default position.

ZHP's counsel refused to discuss more than a handful of individual custodians, despite telling Plaintiffs that they had spoken to their clients about everyone on their list. Instead, the ZHP Defendants' counsel told Plaintiffs that they had to agree to limit their list to fifty custodians before the ZHP Defendants would provide the information needed to consider narrowing the list further.

On December 2, 2019, as described above, ZHP produced organization charts for its Xunqiao Facility and notified Plaintiffs that ZHP would not be providing English translations. As explained above, this violates the Court's order requiring ZHP to provide Plaintiffs with English translations of its organization charts by November 15, 2019.

Two days later, at Plaintiffs request, the Parties held a telephonic meet-and-confer. Based on their ongoing analysis, Plaintiffs asked ZHP to confirm that two proposed custodians were not involved with Valsartan. ZHP confirmed that the superior was not involved in Valsartan but could not confirm whether the subordinate was or not. Plaintiffs nevertheless

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agreed to withdraw both custodians. ZHP then asked Plaintiffs to withdraw four custodians because they had left the company and ZHP no longer had any of their emails: (1) Chunmin Xu, Vice President of Manufacturing, who left ZHP in 2015, and is identified as Valsartan Personnel in ZHP's 2012 Valsartan DMF, (2) Kai Yang, Technical Manager, who left ZHP in 2014, and is identified as Valsartan Personnel in ZHP's 2012 Valsartan DMF, (3) Ruqi Yao, Factory Assistant Direct, who left ZHP in 2012, and is identified as Valsartan Personnel in ZHP's 2012 DMF, and (4) Jieyun Wang, Director of Quality Assurance, who left ZHP in 2008, and is identified as Valsartan Personnel in ZHP's 2007 DMF. The absence of emails for custodians who left as recently as 2015 is very troubling. When asked, ZHP could not say whether ZHP had any other electronic or physical records for these custodians. ZHP could not confirm that ZHP had emails for all other custodians on Plaintiffs' list.<sup>29</sup>

Lastly, after much back and forth, the ZHP Defendants eventually agreed to start discussing individual custodians that they had yet to specifically agree to or dispute, but this was largely unhelpful. Despite being provided a document in Core Discovery containing the custodian's name and additional information, ZHP had not been able to identify Qing Wang, also known as Wangqing. Surprisingly, ZHP said it had not been able to identify XiaXia Kuang, who appears on its own organization charts, and for which Plaintiffs provided reference to a Core Discovery document. When asked about another potential custodian, ZHP said that it did not know what work Jun Wang had done on Valsartan. Plaintiffs then asked about Chun Yang's involvement with Valsartan, but ZHP announced that it would no longer answer Plaintiffs'

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<sup>29</sup> This demonstrates the need for Plaintiffs to obtain document preservation policies and a full understanding of ZHP's electronic data storage systems – i.e., were emails saved to back-up systems?

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questions about individual custodians. The ZHP Defendants did tell Plaintiffs that six custodians had no involvement with Valsartan. Plaintiffs consequently withdrew those custodians.

Despite the minimal cooperation from ZHP, Plaintiffs have methodically constructed the proposed list of custodians from the ZHP Defendants. Each person listed is believed to be necessary to ensure that the custodial searches will capture the relevant, probative documents. ZHP will undoubtedly focus on the number of custodians proposed, maintaining that the arbitrary limit should be 50. However, the proposed list is reasonable here, and it is likely that as Plaintiffs' knowledge base grows there will be good cause to add custodians, including some who were initially listed and then deleted from the initial list in an effort to streamline. The proposed list includes 93 employed by ZHP (including Jun Du who holds positions with multiple ZHP owned entities), - with 28 agreed to, 7 from Huahai US<sup>30</sup> – with 3 agreed to, 12 from Princeton<sup>31</sup> – with 5 agreed to, 5 from Solco<sup>32</sup> – with 4 agreed to, 1 from Syncores – with 0 agreed to, and 10 from Prinbury – with 0 agreed to.<sup>33</sup> The custodians in dispute include executives who will know about important decisions and communications, including through direct involvement, briefings and presentations, the top managers and deputies in key departments such as manufacturing, quality assurance, and regulatory, and those performing the key day to day tasks such as testing the manufactured product for purity and contamination. Of significance, to the extent multiple employees with the same or similar job description and responsibility related to

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<sup>30</sup> 3 overlap with other ZHP subsidiaries.

<sup>31</sup> 4 overlap with other ZHP subsidiaries.

<sup>32</sup> 3 overlap with other ZHP subsidiaries. Due to all this overlap, the ZHP Defendants have agreed to a total of 7 individual custodians from the U.S. subsidiaries.

<sup>33</sup> Plaintiffs have not received any organization charts from Huahai US, Princeton, Solco, Syncores, or Prinbury.

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valsartan were included, this was absolutely necessary since ZHP was unable to provide any information differentiating their knowledge or roles, or to provide any actual data based on an actual review of custodial files. Rather, the ZHP strategy is to resist and hope the Court “splits the baby.”

As set forth on the spreadsheet submitted to the Court, Plaintiffs have provided a basis for inclusion of each person, and ZHP has failed to provide the substantive information needed by the Plaintiffs or the Court to delete a proposed custodian in light of Plaintiffs’ good faith proffers. In fact, after beginning this process with the assertion that only eight custodians were necessary and continuing to resist inclusion of someone as obviously necessary as Jun Du, ZHP’s arguments cannot be credited. Even now, ZHP continues to insist on an arbitrary limitation of the number of custodians, while its production of organization charts remains incomplete - punctuated by the brazen announcement days ago that ZHP would not provide the ordered translations of their organization charts.

ZHP’s effort to obstruct inclusion of necessary custodians should be rejected. Plaintiffs request entry of an Order adopting Plaintiffs’ proposed list of custodians.

## **2. Mylan**

The Parties have conducted several meet-and-confers regarding appropriate custodians. As of the time of this briefing, Mylan has agreed to 27 custodians related to their API manufacturing facilities. Plaintiffs are working to identify any additional custodians related to the API manufacturing functions they wish to add. As of December 5, 2019, Mylan has not provided any potential custodians from their finished dose manufacturing facilities (aside from those custodians with global responsibilities included both API and Finished Dose

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manufacturing). Mylan has not produced any organizational charts for their finished dose facilities, but has committed to producing whatever organizational charts do exist for their three finished dose manufacturing facilities. The Parties intend to settle any and all issues related to the selection of finished dose custodians prior to the December 18, 2019, deadline.

### **3. Teva**

As of another meet-and-confer yesterday, the parties have agreed to 32 Teva custodians. Teva has committed to providing additional information about several other custodians identified by Plaintiffs. Plaintiffs, in turn, have dropped their request for a number of individuals to be custodians, and are evaluating whether they can do so for others. The Parties intend to confer again next week and to settle any and all issues related to custodians prior to the December 11 case management conference, or the December 18, 2019 deadline.

### **4. Hetero USA**

There is currently no dispute as to Hetero USA custodians. Plaintiffs and Defendants have agreed to a list that is without prejudice to Plaintiffs requesting more custodians upon further discovery developments. This list also does not include any other Hetero-affiliated entities' custodians to be negotiated at a later date.

### **5. Aurolife**

Because Aurobindo Pharma, Ltd. has not yet been served, the only negotiations over custodians which have taken place relate to the United States finished dose manufacturing entity, Aurolife Pharma, LLC, and Aurobindo Pharma USA, Inc. As a result of meet-and-confer sessions, the Parties have reached agreement as to thirteen custodians:

1. Jeffrey Jackowski

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2. Blessy John
3. Daniel Burns
4. Sandra Martinez
5. Bhadresh Doshi
6. Jasleen Gupta
7. Steve Lucas
8. Milind Shirshikar
9. Prasad Gorijavolu
10. Krishna Reddy Chada
11. Sudhir Bheeminemi
12. David Palew
13. Venkata Kota

The following custodians remain in dispute:

**a) Srinivasulu Ale (former Aurolife Director of Quality Control)**

Defendants contend Mr. Ale was allegedly “not actively involved with the products at issue or the recall.” Ex. 28. However, this is contradicted by documents produced in Core Discovery, which show that Mr. Ale was interviewed as part of the 2016 EIR. *See* AURO-MDL 2875-0077801; AURO-MDL 2875-0077725. As the Director of Quality Control, Mr. Ale was assigned multiple topics on Day 2 of the inspection, including Out of Specification issues, ANDA deficiencies, and stability review, among other things. *See* AURO-MDL 2875-0077726.

**b) Amman Aysha (former APUSA Pharmacovigilance Manager)**

Defendants indicated that Dr. Aysha “was not involved with the products at issue or the recall. She was replaced by Jasleen Gupta.” (Ex. 28) That Defendants agreed to add Jasleen Gupta only serves as further evidence for why Dr. Aysha should also be a custodian. Dr. Aysha had substantial involvement with Valsartan and particularly postmarket surveillance. Dr. Aysha was interviewed as part of the 2018 EIR, specifically for her involvement with pharmacovigilance, which is a subject into which discovery is appropriate. *See* AURO-MDL

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2875-0077740. Moreover, the 2018 EIR resulted in a finding by the FDA that Voluntary Action was Indicated and mentions Valsartan numerous times. *See generally* AURO-MDL 2875-0077740. For the same reason the Parties agree that Jasleen Gupta is appropriate, Dr. Aysha should also be added as a custodian.

**c) Chintal Thakkar (Regulatory Affairs)**

Defendants indicated that Ms. Thakkar reported to Blessy John and that “[s]he was not involved with the products at issue or the recall.” Ex. 28. However, it appears Ms. Thakkar was involved with Valsartan. Indeed, Chintal Thakkar was the person who signed the ANDA submitted in 2018 for Valsartan on behalf of Blessy John, indicating that she also had a great deal of responsibility and likely has documents and communications independent from what made its way to her supervisor. (Auro-MDL 2875-0018874). Moreover, the 2018 EIR indicates that Chintak Thakkar was involved with the Valsartan contamination issue, as she was interviewed by the FDA. *See* AURO-MDL 2875-0077747. While Blessy John was also interviewed, it is telling that the FDA inspector decided to interview them both independently. For this reason, Plaintiffs request that she also be added as a custodian.

**d) Arpit Patel (Associate Director of Quality Assurance)**

According to Defendants, Mr. Patel “was not actively involved with the products at issue or the recall.” The documents produced in Core Discovery indicate otherwise. Arpit Patel was integrally involved in the 2016 EIR, and the FDA inspector noted that he, along with Dr. Kota, were charged with guiding the FDA inspector throughout the inspection. *See* AURO-MDL 2875-0077722. The rest of this document mentions Arpit Patel repeatedly as a critical part of the

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process. Dr. Patel was also charged with escorting the FDA inspector around Aurolife's facilities throughout the 2015 FDA inspection. *See* AURO-MDL 2875-0077785.

Plaintiffs respectfully contend that these custodians should be added.<sup>34</sup>

## **6. Torrent**

The Parties have agreed to 15 total custodians. Torrent has also indicated that it needed to continue to request additional information regarding certain departments and potential custodians. As such, the list is currently in flux, however Torrent has committed to obtaining this subsequent information by December 18, 2019, at the latest.

Nevertheless, Plaintiffs have identified an additional set of custodians they wish to add to the final list. Torrent has indicated it would object to any of these additional custodians on the basis that these custodians are duplicative of other agreed upon custodians, and that Torrent would face an undue burden in producing these documents.

With respect to Torrent's argument as to duplicative custodians, Plaintiffs believe this argument is without merit. Employees within the same division almost always have discrete and unique responsibilities which do not make these custodians duplicative. Furthermore, Plaintiffs endeavored to only include custodians from the same division to the extent they were at different hierarchical levels in the department. For many of the custodians which Torrent has indicated it would object to on the basis that they are duplicative and/or would present an undue burden to

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<sup>34</sup> Plaintiffs reserve all rights to ask for additional custodians from any Auro entity once Aurobindo Pharma Ltd. has been served and provides documents which shed light on the interaction between the various Auro entities. Plaintiffs have not been permitted sufficient discovery into this at this time to feel confident that all necessary custodians have been selected.

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produce, Torrent has not provided information that these custodians did not have responsibility for the testing or quality assurance functioning related to Valsartan.

Because the process is ongoing, and in light of the nature of Torrent's objections, Plaintiffs believe setting a specific custodian cap of 25 custodians is the appropriate relief necessary to allow the parties to continue to meet-and-confer. This will provide Plaintiffs the assurances that they will be able to add some subsection of additional custodians, but will provide Defendants the time to continue gathering necessary information from employees headquartered in India.

**C. Search Terms**

Courts generally agree that one of the best ways to resolve the scope of a responding party's compliance with a discovery request is for the parties to agree on a list of search terms.<sup>35</sup> With increasing frequency, courts order parties and nonparties to negotiate and agree upon proposed search terms, and require a producing party to provide information necessary for the requesting party to develop appropriate search terms, such as organizational charts and sample documents. *See, e.g., McNulty v. Reddy Ice Holdings, Inc.*, 271 F.R.D. 569, 571 (E.D. Mich. 2011).

While Defendants have balked at the number of terms Plaintiffs propose, they have done so based on nothing more than speculation that one or more terms *may* result in too many

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<sup>35</sup> *See, e.g., SEC v. Collins & Aikman Corp.*, 256 F.R.D. 403, 414-15, 418 (S.D.N.Y. 2009); *Romero v. Allstate Ins. Co.*, 271 F.R.D. 96, 109 (E.D. Pa. 2010); *William A. Gross Const. Associates, Inc. v. American Mfrs. Mut. Ins. Co.*, 256 F.R.D. 134, 136 (S.D.N.Y. 2009); *see also* Thomas Y. Allman, Conducting E-discovery After the Amendments: The Second Wave, 10 SEDONA CONF. J. 215, 216 (2009) (noting that "cooperation among parties in [e-]discovery has emerged as a decisive mandate").

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irrelevant documents. This is an improper basis to reject the use of an otherwise valid search term. Moreover, courts routinely approve the use of a far greater number of appropriate search terms in complex cases such as this one. *See, e.g., In re Fannie Mae Securities Litig.*, 552 F.3d 814, 817-21 (D.C. Cir. 2009) (affirming use of over 400 search terms).

Discovery in general should be a combined cooperative effort. Parties must disclose certain information, including categories of Electronically Stored Information that the disclosing party has in its possession, custody or control and may use to support its claims or defenses. Fed. R. Civ. P. 26(a). “Parties are expected to reach agreements cooperatively on how to conduct discovery under Fed. R. Civ. P. 26-36.” *See* D. Del. Default Standard for Discovery, Std. 1. The Sedona Conference implemented the Cooperation Proclamation (2008) stating it is “a mandate for counsel to act cooperatively.” and collaborate in a transparent discovery process. The Sedona Conference® Cooperation Proclamation, 10 SEDONA CONF. J. 331 (2009). “Courts expect parties to reach practical agreement on search terms, date ranges, key players, and the like.” *Id.* at 217. *See also, DeGeer v. Gillis*, 755 F. Supp. 2d 909, 929 (N.D. Ill. 2010) (“Selecting search terms and data custodians should be a matter of cooperation and transparency among parties and non-parties.”);

Plaintiffs have proposed a comprehensive but reasonable set of primary search terms (Ex. 29) and modifiers (Ex. 30),<sup>36</sup> taking into account that this litigation involves numerous

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<sup>36</sup> The two spreadsheets represent categories of primary search terms and categories of modifiers. Each primary search term tab in the Primary Search Terms spreadsheet contains, to the right of the terms list, the query to be used. Thus, for example, the Manufacturing tab has the search structure “<term> AND (<drug name> or <solvent>).” Thus, the terms listed on the Manufacturing tab would result in a hit if they appeared in the same document as any term on the Drug Names modifiers tab or the Solvents modifiers tab, but would not result in a hit if the term

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defendants, each with their own individual manufacturing facilities and practices including defendants and facilities located worldwide, and further involves the inter-relationship between some of those defendants. Further, the products at issue have over a decade of manufacturing history, implicating regulatory issues and oversight, multiple disparate processes, multiple medical issues caused by the contamination, and an as yet undetermined methodology or methodologies for the contamination, collectively multiplying the universe of relevant search terms. As the Court acknowledged on November 20, 2019, Plaintiffs' are not bound by the FDA's "prevailing theories and assumptions" on the method of contamination and must be allowed to review the underlying information in order to reach their own conclusions. In addition, the issue of notice is also crucial in this litigation. Thus, while terms related to when defendants knew or should have known about that contamination are key, terms related to when defendants should have been on inquiry notice that the process used for manufacture could lead to contamination are also essential for a central issue in the case.

Defendants have the burden to establish that the Plaintiffs' search terms, a form of discovery request, would be unduly burdensome when compared to the alternative offered by the Defendants and disproportional to the needs of the case, which they cannot. In fact, the Defendants have not presented a counter-proposal in the MDL based upon any evidence of actual burden or disproportionality.

The fundamental dispute here is as a result of the Defendants' repeated failure to adequately meet-and-confer and provide requested information to aid in the possible refinement

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appeared by itself, or solely in conjunction with one of the terms on any of the other modifiers tabs.

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of Plaintiffs' proffered search terms. As a preliminary matter, Defendants have not proffered a single suggested search term based upon their internal usage. Nor have they produced internal documents (that is, documents that were not communications to or from the FDA) that would help Plaintiffs identify such internal usage. In every pharmaceutical case Plaintiffs' counsel has been involved in, Defendants have had their own company or even department specific internal acronyms and shorthand, by which they refer to certain drugs, ingredients, tests, processes, departments, document categories, or problems. Defendants also generally have internal project names associated with the research and development of new or revised manufacturing processes, cost saving efforts, etc. It defies belief that not a single one of the Defendants involved in this litigation has used any such company or department specific term, yet despite repeated requests, Defendants have not provided even a single one. *See William A. Gross Const. Assocs., Inc. V. Am. Mfrs. Mut. Ins. Co.*, 256 F.R.D. 134, 136 (S.D.N.Y. 2009) ("where counsel are using keyword searches for retrieval of ESI, they at a minimum must carefully craft the appropriate keywords, with input from the ESI's custodians as to the words and abbreviations they use"); *See also* the declaration of Plaintiffs' ESI consultant, Jonathan Jaffe ("Jaffe Decl.") (Ex. 31).

The other central impediment imposed by Defendants is their failure and refusal to collect any custodial documents to run test searches and generate hit counts until the parties have reached a final agreement on all custodians, even though Defendants themselves had identified specific custodians months ago whom they believed were key custodians with documents relevant to issues in the litigation. Thus, the entire search term negotiation process has been conducted in a factual vacuum. Defendants have simply argued that the terms proposed by Plaintiffs were, on their face, too burdensome, without any support from the normal process of

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generating hit counts and sampling underlying documents to determine whether or not a particular term (potentially with modifiers) is really too burdensome. *See In re Lithium Ion Batteries Antitrust Litig.*, 2015 WL 833681 (N.D. Cal. 2015) (Ex. 35) (“Plaintiffs argue that qualitative sampling will provide insight into why a seemingly relevant search term may be returning disproportionate numbers of irrelevant documents. This process could lead to search adjustments, which would improve precision in identifying relevant documents.”); *See also* Jaffe Decl. (Ex. 31).

These refusals have led to significant knowledge gaps on the part of Plaintiffs vis-as-vis Defendants and has resulted in significant wasting of time and energy during the meet-and-confer process. Nevertheless, in the spirit of cooperation, Plaintiffs have made significant changes to their initial proposed search terms by narrowing and categorizing specific lists of modifiers to be used with specific categories of primary search terms as well as adding additional modifiers to individual search terms. The parties are now, however, at an impasse because Defendants have provided Plaintiffs with no factual bases, such as hit counts and document sampling, by which Plaintiffs can intelligently make decisions on whether any of the terms and/or modifiers should be narrowed further.

Defendants negotiating posture regarding search terms has been that other than a small number of standalone terms that they agree with, all other terms must be run with at least the drug name modifiers, in addition to additional modifiers. While Plaintiffs are in agreement that

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certain terms should be run with modifiers, Plaintiffs disagree that virtually all terms must be run with drug name modifiers for four fundamental reasons<sup>37</sup>:

First, the issue of contamination in the case, even under the FDA's prevailing theory, deals with contamination caused by the use of solvents during the API manufacturing process, including reclaimed or recycled solvents. Thus there is significant relevant discovery that will most likely deal solely with discussions of the underlying solvent, the process changes associated with changing solvents, the use and testing of reclaimed or recycled solvents, etc., none of which would necessarily include a drug name in the underlying document. Hence, in most cases, Plaintiffs have proposed running categories of search terms against both the drug name modifiers list and solvent modifiers list rather than just the drug name modifiers list. *See* Exs. 29 and 30.

Second, many of the issues in the case involve inspections of Defendants' manufacturing facilities by the FDA and other agencies. These inspections are generally drug specific, and the quality control and assurance issues identified would not necessarily be identified with a specific drug or process, nor would the Defendants' internal discussions regarding those issues. Thus, Plaintiffs have proposed running limited categories of search terms against a broader list of terms that go beyond just drug names and solvents as modifiers. *See* Ex. 29 and 30.

Third, these search terms will be directed only to custodians with information relevant to the litigation. Thus, crucial terms relevant to the case, such as NDMA, NDEA, and variations on that term, DMF, the key solvent identified by the FDA as the potential cause of the contamination, chemical formulas for those chemicals and solvents and intermediate steps in the formation of the contaminants, etc. are all terms that, Plaintiffs contend, should be run without

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<sup>37</sup> *See also* Jaffe Decl. at Ex. 31.

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modifiers in order to pick up potentially crucial documents from those custodians that may not contain the drug name *See* Ex. 29 (Standalone primary list). Further, experience shows that individuals at a company do not generally mention a drug name in communications because the individuals involved already know the subject matter involved, and they have most likely also been discussing the same issue orally. Thus, for certain categories of primary search terms plaintiffs have added additional modifiers other than the drug name and solvent to try and capture these types of documents. *See* Ex. 29 (Regulatory, QA-Testing, and cGMP primary list).

Finally, with regard to the Authors and Inspectors list, Plaintiffs believe that the majority of these names, which are relatively unique, should be run without modifiers because of the key nature of these individuals, which were either inspectors that Plaintiffs have been able to determine were actually involved in inspections of Defendants' relevant manufacturing facilities, or were named authors on publications dealing with the contamination of valsartan at issue in the case. Where the individual's name appears to be more common, Plaintiffs have proposed running it in conjunction with the individual first name, or with the names of the regulatory agencies for whom they worked. Defendants, by refusing to collect documents and run hit reports and sample those results have, unfortunately, made it impossible for Plaintiffs to narrow these terms further with regard to disambiguation of particular individuals by, for example, excluding the full name and e-mail address of specific irrelevant individuals.

Given the constraints faced by Plaintiffs due to the lack of data regarding company specific terms, hit reports, and document sampling, Plaintiffs have done the best they could to narrow the search terms to a manageable and relevant set, with the use of modifiers for the vast majority of the terms to limit the results to relevant documents. Plaintiffs have repeatedly asked

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Defendants to provide them with additional information that would have allowed them to intelligently further narrow terms and modifiers, if necessary, but Defendants have refused to do so. The Court has made it crystal clear that it expected to rule on all outstanding discovery issues, and specifically search terms, at the December 11, 2019 hearing. Thus, given that Defendants cannot show any specific burden or disproportionality with regard to the search terms and modifiers proposed by Plaintiffs, Plaintiffs respectfully ask the Court to adopt and order the search terms and modifiers as proposed by Plaintiffs. Plaintiffs also respectfully submit that the Court should order that Plaintiffs are allowed to supplement the current list of search terms with any company specific terms, such as acronyms, short forms, or code names, that may become evident as discovery progresses.

**D. Defense Information Re: ESI and Physical Document Storage**

Despite the Court's Order of November 7, 2019 requiring the Parties to meet in person regarding ESI and document storage information, Plaintiffs continue to seek a substantial completion to Plaintiffs' request for background information on the manner in which physical and electronic material are stored and organized within the corporate entities of each Defendant.<sup>38</sup> Although technical in nature and as phrased, the questions Plaintiffs are asking are simple and fundamental to the issues at the heart of this case and include for example: Do you have written policies governing how long material is kept? Do you have electronic catalogs for

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<sup>38</sup> Plaintiffs outlined their original request for background information on physical materials and ESI systems on 4/8. Subsequent to that, Plaintiffs further tailored their request on 11/11 in advance of the in person ESI meetings as ordered by the Court on 11/7. Plaintiffs received a written response from Defendant Mylan on 11/6. Plaintiffs met and conferred with Defendants Mylan, Torrent, Teva and ZHP on 11/15 in Philadelphia. Plaintiffs received a written response from Defendant Aurobindo on 11/13. Plaintiffs conferred by phone with Defendant Aurobindo on 11/19 and 11/22. Plaintiffs received a written response from Defendant Hetero on 11/27.

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test results and physical test samples? Do you, and if so how, retain documents that you showed the FDA upon inspection? How do you communicate with your foreign entities? In what systems do you keep specifications? In what systems do you keep changes to your processes? In what systems do you keep your testing results and for how long? Do you have a system for documentation of your good manufacturing processes? Do you have a system for documentation of corrective and preventive actions (CAPAs)? What system do you use for reports of adverse events?

Unfortunately, while pursuant to the Court's Order, the Parties (specifically Defendants Mylan, Teva, ZHP, Torrent) did meet in Philadelphia or over the phone (Aurobindo),<sup>39</sup> and while Plaintiffs did outline in April, and again in November, the areas that would be covered, only one Defendant (Mylan) even brought someone who was not solely outside counsel to the meeting, and that was someone who had been Mylan's inside counsel. Unlike Defendants, Plaintiffs brought their outside ESI consultant, Mr. Jonathan Jaffe, to the in person meeting, and have had him participate on every subsequent phone calls. *See Jaffe Decl.* (Ex. 31).

More concerning than the just the lack of participation by company representatives, however, was that the outside counsel present for these conferences, having eschewed bringing a company representative, were ill prepared to cover the outlined topics. For many topics, they simply did not know the answer. Even worse, for other topics they were clearly speculating.<sup>40</sup> Despite the meetings having occurred mid-November and despite promises to provide additional

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<sup>39</sup> Defendant Hetero has only provided a written response.

<sup>40</sup> Technical data is all fact based. Either a company has employed certain systems or it has not. Either retention policies and schedules exist or they do not. If Plaintiffs get incorrect information, Plaintiffs' requests will be based upon that misinformation. That results in unnecessary frustration and expense for both parties.

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information on areas still outstanding as outlined at the meetings and on phone conversations, to date Defendants have not provided any substantial additional information on their systems or processes. *See* Jaffe Decl. (Ex. 31).

As this Court recognized in ordering the in person meeting, this background information critically impacts a number of discovery issues going forward and has prejudiced Plaintiffs' ability to more narrowly tailor both custodians and search terms. For example, Plaintiffs learned during the meetings that one defendant only retains emails for one year, another for only two years, another for only 120 days before email is moved to archived systems, and one indefinitely. For two groups of Defendants, we do not know how long they retain email at all. Yet, Plaintiffs still do not know, for many Defendants, answers to important questions like what happened to the emails of people who left the company? What happened to emails that were on litigation hold due to another litigation? Knowing this information allows Plaintiffs to appropriately tailor requests and identify custodians, without this, Plaintiffs have to paint with a broader brush. Knowing whether certain information (such as CAPAs, test results, etc.) are centrally stored and catalogued or only kept by individual custodians, again, allows Plaintiffs to tailor requests, search terms, and limit or expand custodian lists. Knowing the software and systems used in testing the API and finished dose allows Plaintiffs to consult their experts on the best way to request the information they will need to form opinions (e.g. native format, exported to a database, exported to a spreadsheet). Defendants continued apparent refusal to actually engage in this process of providing information is perplexing, to the say the least. *See* Jaffe Decl. (Ex. 31).

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Plaintiffs respectfully request that the Court again order the Defendants to meet in person with Plaintiffs, this time with their company representatives with knowledge of the required information present, so that this information can be obtained and the issues resolved.

## **II. CONCLUSION**

For the foregoing reasons, the Court should overrule Defendants' amended objections to Plaintiffs document requests identified above, order Defendants to apply Plaintiffs' proposed search terms to the ESI collected from Plaintiffs' proposed custodian lists, and to order Defendants (again) to meet with company representatives with knowledge of the required systems information.

Respectfully,

A handwritten signature in blue ink, appearing to read 'Adam M. Slater', written over a horizontal line.

ADAM M. SLATER

AMS

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**CERTIFICATE OF SERVICE**

A true and correct copy of the foregoing was filed and served this 5<sup>th</sup> day of December 2019 on all counsel of record via the CM/ECF system of the United States District Court for the District of New Jersey.

/s/ Adam Slater  
Adam Slater